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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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BOSTON MA 02109

HM12/0111

EXAMINER

BRANNOCK, M

ART UNIT	PAPER NUMBER
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1646

Handwritten number 32.

DATE MAILED:

01/11/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
08/900,220

Applicant(s)
Miao, N. et al.

Examiner
Michael Brannock, Ph.D.

Group Art Unit
1646



☒ Responsive to communication(s) filed on Nov 17, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-35, 39-43, 47-49, and 52-71 is/are pending in the application.

Of the above, claim(s) 1-34, 41, 47, 48, 55-61, and 71 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 35, 39, 40, 42, 43, 49, 52-54, 62, 63, 65, 67, 69, and 70 is/are rejected.

☒ Claim(s) 64, 66, and 68 is/are objected to.

☒ Claims 1-35, 39-43, 47-49, and 52-71 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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DETAILED ACTION

Status of Application: Claims and Amendments

1. The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Michael Brannock, Group Art Unit 1646.
2. Applicant is notified that the amendments put forth in Paper 29 (received 11/16/2000), have not been entered in full. Specifically, the proposed amendments of page 63, lines 32 and 33, were not entered because the term "GTCGCC" is not present at either line 32 or line 33. However, the amendments to page 63, lines 32 and 33, as put forth in Paper 30, 12/13/00, have been entered in full.
3. Claims 1-35, 39-43, 47, 48, 49, 52-71 are pending.
4. Claims 1-34, 41, 47, 48, 55-61 and 71 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention, the requirement having been traversed in Paper No. 19.

Applicant argues that the claims of Group IV are classified in the same class of provisionally elected Group I, and thus, searching this additional class would not place an undue

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burden on the examiner. This argument has been fully considered but not deemed persuasive because the classification of the methods and preparations of Group I, provisionally classified by the examiner as 536/23.1 is only a partial classification directed to one embodiment of the claims, i.e. nucleic acids which may be used to practice the invention. The classification of Group I, as a whole, would also include 514/44 and 514/2, among others. Thus, a search solely of the claims of Group IV could not be relied upon to provide art relevant to Group I. The two searches would overlap, but they would not be coextensive; and to search both in one application would be burdensome.

Response to Amendment

Withdrawn Objections/Rejections:

5. Applicant is notified that the application appears to be in full compliance with the rules of regarding sequence disclosures.
6. The rejection of claims 35-40, 42, 49-54, 62-70 and 72-74 under 35 USC 101, as put forth on page 4 of Paper 28 is withdrawn in view of the cancellation of relevant claims and in view of further consideration and Applicant's persuasive arguments in Paper 29 regarding the prior art teaching utility for the claimed polynucleotides.

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7. The rejection of claims 49, 52, 53, 54, 62, 64, 66, 67 and 68 under 35 USC 112, first paragraph, as set forth in item 4 of Paper 28, is withdrawn in view of the cancellation of relevant claims and upon further consideration, i.e., in view of the finding that the specification contains an adequate written description of the polynucleotides of SEQ ID NO: 7 and 8, encoding the polypeptides of SEQ ID NOs: 16 and 17, respectively.

8. The rejection of claims 35-38 and 44-46 under 35 USC 102(b), as set forth in item 6 of Paper 28 is withdrawn in view of the cancellation of relevant claims and in view of Applicant's amendments to limit the claims to at least 98% identity of SEQ ID NO: 17.

9. The rejection of claims 35-40 and 42-46 under 35 USC 102(b), as set forth in item 7 of Paper 28 is withdrawn in view of the cancellation of relevant claims and in view of Applicant's amendments to limit the claims to at least 98% identity of SEQ ID NO: 17.

10. The rejection of claims 38-46, 49-54, 64-66, 68-70 and 72-4 under 35 USC 102(b), as set forth in item 7 of Paper 28 is withdrawn in view of the cancellation of relevant claims and in view of Applicant's amendments to limit the claims to at least 98% identity of SEQ ID NO: 17.

Note that the rejection is maintained for claims 63 and 67, see below.

Maintained Objections/Rejections:

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11. Claims 35, 39, 40, 42, 43, 63, 65, 69 and 70 stand rejected under 35 USC 112, first paragraph, as set forth in item 4 of Paper 28. The specification discloses polynucleotides of SEQ ID NO: 7 and 8, yet the claims encompass polynucleotides not described in the specification, e.g., sequences from additional species, mutated sequences, allelic variants, or sequences that have a recited degree of identity. The multitude of these sequences do not meet the written description provision of 35 U.S.C. 112, first paragraph. Although one of skill in the art would reasonably predict that these sequences exist, one would not be able make useful predictions as to the nucleotide positions or identities of those sequences based on the information disclosed in the specification.

With the exception of the of the polynucleotides of SEQ ID NO: 7 and 8, the skilled artisan cannot envision the detailed chemical structure of the encompassed variants. Therefore, only the polynucleotides of SEQ ID NO: 7 and 8, and polynucleotides *consisting* of fragments thereof, but not the full breadth of the claims meet the written description provision of 35 U.S.C. §112, first paragraph.

Applicant argues, on page 8 of Paper 29, that the written description issue is not relevant to SEQ ID NO: 17 or fragments thereof. The examiner agrees and notes that those claims that are limited to SEQ ID NO: 7, 8, 16, 17, or fragments of SEQ ID NO: 7, 8, 16, 17 have been removed from the rejection. However, claims 35, 39, 40, 42, 43, 63, 65, 69 and 70 encompass an almost limitless number of variants of the disclosed sequences - the vast majority of such variants are not supported by an adequate written description.

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Additionally, as set forth in item 4 of Paper 28, the specification does not provide sufficient enabling basis to allow the skilled artisan to *make* a polynucleotide encoding an amino acid sequence variant of the polypeptides of SEQ ID NOs: 16 and 17 that still retain any asserted properties of the polypeptides SEQ ID NOs: 16 and 17. Conversely, the specification has failed to teach one of skill in the art how to *use* a polynucleotide encoding an amino acid sequence variant of the polypeptide of SEQ ID NO: 16 or 17 that does not have any asserted properties of the polypeptides SEQ ID NOs: 16 and 17.

Applicant's arguments concerning the prior art references of Bigood et al., and Ingham et al., have been considered and deemed persuasive regarding enablement of SEQ ID NO: 7, 8, 16, 17, or fragments of SEQ ID NO: 7, 8, 16, 17. However, these references do not teach how to make a polynucleotide encoding an amino acid sequence *variant* of the polypeptides of SEQ ID NOs: 16 and 17 that still retains any asserted properties of the polypeptides of SEQ ID NOs: 16 and 17. Nor do these references teach how to *use* a polynucleotide encoding an amino acid sequence *variant* of the polypeptide of SEQ ID NO: 16 or 17 that does not have any asserted properties of the polypeptides SEQ ID NOs: 16 and 17.

12. Claims 63 and 67 stand rejected under 35 U.S.C. 102(b) as being anticipated by Hillier et al., Genome Res. 6(807-828)1996, for the reason set forth in item 8 of Paper 28. Given the broadest reasonable interpretation of the claims, claims 63 and 67 do not require that the recited polypeptide be full length SEQ ID NO: 17, nor that the polypeptides have any functional

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limitation. Therefore, the breadth of the claims can reasonably be considered to include Desert hedgehog proteins that are derived from the full length protein, e.g. antigenic fragments. As set forth in item 8 of Paper 28, Hillier et al. disclose a polypeptide that is a fragment of SEQ ID NO: 17.

Applicant argues that the reference is non-enabling. This argument has been fully considered but not deemed persuasive because the reference discloses a product which is an embodiment of the claims; thus there is no requirement that the reference teach how to use the product.

New Objections/Rejections:

13. Claim 43 is objected to because of the following informalities: The claim requires a period at the end of the last line. Appropriate correction is required.

14. Claim 35 is objected to because of the following informalities: The claim has a misplaced bracket at line 4. Appropriate correction is required.

15. Claims 35, 39, 40, 42, 43, 49, 52, 53, 54, 62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 35, and dependent claims 39, 40, 42, and 43, are rejected because claim 35 has a misplaced bracket at line 4, therefore the metes and bounds of the claim cannot be determined.

Claim 49, and dependent claims, require that the polypeptide bind "to patched", whereas claim 35 requires that the polypeptide bind "to a patched protein". The wording of claim 49 implies that "patched" is a particular example of a patched protein. It is unclear what applicant considers "patched" to be, i.e. what distinguishes the patched protein of claim 49 from that of all of the other patched proteins encompassed by claim 35. Therefore, the metes and bounds of claim 49 cannot be determined.

Allowable Subject Matter

16. Claims 64, 66, and 68 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brannock, Ph.D., whose telephone number is (703) 306-5876. The examiner can normally be reached on Mondays through Fridays from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MB



January 10, 2001

David Rames
Primary Examiner